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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,426	07/22/1999	ALLAN WILLIAM CRIPPS	064727.0105	2788

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/359,426	Applicant(s) CRIPPS ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7, 9, 18, 20-22, 24-27, 36 and 37 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 7, 18, 20, 21, 24, 26 and 37 ~~is/are~~ are allowed.
- 6) ☒ Claim(s) 9, 22, 25, 27 and 36 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendments filed 08/06/04 in response to the non-final Office Action mailed 02/18/04.

Status of Claims

- 2) Claims 9, 18, 36 and 37 have been amended via the amendment filed 08/06/04.
Claims 1, 7, 9, 18, 20-22, 24-27, 36 and 37 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Withdrawn

- 5) The rejection of claims 9, 22, 25, 27 and 36 made in paragraph 19 of the Office Action mailed 02/18/04 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is withdrawn. A modified new matter rejection is made below to address the claims, as amended.

Applicants cite *Guidelines for Examination of Patent Application under the 35 U.S.C., first paragraph, Written Description Requirement*, 66 FR 1099, 1106 and contend that an Applicant may show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that Applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

It should be noted that the rejection of claims 18, 20 and 26 made in paragraph 20(a) of the Office Action mailed 02/18/04 under 35 U.S.C § 112, first paragraph, was a new matter rejection, but not a rejection made due to inadequate written description.

- 6) The rejection of claims 18, 20 and 26 made in paragraph 20(a) of the Office Action mailed

02/18/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

7) The rejection of claim 37 made in paragraph 20(c) of the Office Action mailed 02/18/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

8) The rejection of claim 9 made in paragraph 20(b) of the Office Action mailed 02/18/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicants cite case law and state that the test for definiteness is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." Applicants submit that the specification, as originally filed, makes clear that any such fragments "must be" antigenic fragments. Applicants state that lines 12-23 of page 2 of the specification describe varying the sequence of fragments while retaining antigenic properties, and that lines 6, 13, 20, 25, 32 and 34 on page 3 of the specification refer to the use of 'antigenic fragments'. Applicants conclude that it would be clear to one skilled in the art, reading the claims in light of the specification, that enough of the second protein's original structure must be retained in the fragment so as to render the fragment antigenic.

Applicants' arguments have been carefully considered, but are non-persuasive. Contrary to Applicants' assertion, the specification, as originally filed, does not contain a closed definition of the term 'fragment of a second protein'. The specification, as originally filed, does not recite that fragments "must be" antigenic fragments. For instance, line 25 on page 2 and line 1 of page 4 of the specification recite 'fragments' of the antigen or antigenic protein, as opposed to 'antigenic fragments' of the antigenic protein. This is not a closed definition. Furthermore, lines 11 and 12 on page 2 of the specification expressly state that parts or fragments of the whole protein 'may' be antigenic, which is not the same as 'must' be antigenic. Clearly, the fragments of the claimed protein described in the originally filed specification encompass those that are not antigenic. In the absence of a closed or limiting definition within the instant specification, one of skill in the art would not recognize the metes and bound of the term 'fragment'. What constitutes a 'fragment',

and how much of the second protein's original structure has to be retained such that the resulting product can be considered as a 'fragment' is not clear. The metes and bounds of the structure encompassed in the limitation 'fragment' are indeterminate. Does a single amino acid of the second protein qualify as a fragment?

9) The rejection of claims 22, 25, 27 and 36 made in paragraph 20(d) of the Office Action mailed 02/18/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein.

New Rejection(s)

Applicants are asked to note the following new or modified rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments to the claims.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

10) Claims 9, 22, 25, 27 and 36 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 9, as amended, includes the new limitations: 'a second protein wherein said second protein is a *P. aeruginosa* antigen'. The claim also retains the recitation: 'a fragment of said second protein'. However, there is no descriptive support in the specification, as originally filed, for a composition comprising an isolated *P. aeruginosa* protein of molecular weight of about 60 kDa to about 65 kDa and an N-terminal amino acid sequence of SEQ ID NO: 2 which further comprises 'a second protein' or 'a fragment of said second protein wherein said second protein is a *P. aeruginosa* antigen'. Page 2 of the originally filed specification does not provide descriptive support for 'a second protein' (or a third or fourth protein for that matter) or 'a fragment of said second protein wherein said second protein is a *P. aeruginosa* antigen'. Therefore, the above-identified limitations in the claim(s) are considered to be new matter. New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). See M.P.E.P. 608.04 to 608.04(c).

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Applicants are invited to point to the descriptive support in specific part(s) of the disclosure, as originally filed, for the limitations identified above, or to remove the new matter from the claims and/or the base claim(s).

Remarks

11) Claims 9, 22, 25, 27 and 36 stand rejected. Claims 1, 7, 18, 20, 21, 24, 26 and 37 are allowable.

12) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.

14) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may

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be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

October, 2004



S. DEVI, PH.D.
PRIMARY EXAMINER